



24 August 2017

FIELD CORRECTIVE ACTION
Intrabeam PRS 500 – Change of calibration factor in ionization chamber

Dear Sir or Madam,

Thank you very much for using the ZEISS INTRABEAM PRS 500. As you know, high quality and innovation is our main goal, but your safety and satisfaction is our first priority. To ensure that you are able to continue reliably use of our devices with the level of high quality you expect, ZEISS is planning to perform a Field Corrective Action.

As a result of our routine quality inspection we found out that our supplier provided an incorrect documentation of the calculated calibration factors. That means you received an inaccurate PTW calibration certificate for the ionization chamber (PTW TN23342 <SN00...enter correct serial number>) used in the system quality assurance (SQA) tool PAICH of your ZEISS INTRABEAM PRS 500.

The ionization chamber was not calibrated under the usual reference condition TW 30 (PTW) but under TW 15 (PTW).

That means the k_Q correction factor differs in that case from 1.000 at TW 30 (PTW).

Also it is wrongly stated in the calibration certificate that TW 30 (PTW) reference condition was used instead of TW 15 (PTW).

In some cases this can lead to a higher risk that the PAICH SQA procedure measures a deviation in dose output larger than the allowed $\pm 5\%$ which results in a warning message which needs to be acknowledged by the medical physicist expert.

Despite this incorrect ionization chamber calibration certificate it is impossible to deliver an incorrect dose outside the uncertainty margin to the patient. Due to the safety concept of the ZEISS INTRABEAM PRS 500 the possible larger deviation in the dose output will alert the medical physicist expert and needs his active acknowledgment.

To ensure that your system will work with the highest accuracy it is necessary to change the calibration factor in the ZEISS INTRABEAM PRS 500 (Equipment inventory) according to the attached corrected PTW calibration certificate of your chamber. This action will be carried out by a ZEISS Field Service Engineer. It can also be performed by yourself according to the attached procedure (Attachment 1) and the corrected calibration protocol (Attachment 2).



Independent of how you decide to update your device, a member of our service staff will contact you in the coming days in order to schedule a service visit to perform the required update or to verify that the update has already been performed. Meanwhile you can work with your device safely without any limitation.

We apologize for any inconvenience caused and we hope that, by updating your ZEISS INTRABEAM PRS 500, we will be able to satisfy your requirements.

If you have any questions, please feel free to contact your local ZEISS sales representative.

Thank you for your cooperation.

Sincerely,

Attachment:

1. Procedure to update the device
2. Corrected PTW ionization chamber calibration protocol